



FOOD LABELING: Revision of the Nutrition and Supplement Facts Labels

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INTRODUCTION

The Regulatory Studies Program of the Mercatus Center at George Mason University is dedicated to advancing knowledge about the effects of regulation on society. As part of its mission, the program conducts careful and independent analyses that employ contemporary economic scholarship to assess rulemaking proposals and their effects on the economic opportunities and the social well-being available to all members of American society.

This comment addresses the efficiency and efficacy of the proposed rule from an economic point of view. Specifically, it examines how the proposed rule may be improved by more closely examining the societal goals that the rule intends to achieve and by determining whether this proposed regulation will successfully achieve those goals. In many instances, regulations can be substantially improved by choosing more effective regulatory options or by more carefully assessing the actual societal problem.

SUMMARY

Pursuant to the Nutrition Labeling and Education Act (NLEA) of 1990¹ and the Dietary Supplement Health and Education Act (DSHEA) of 1994,² the Food and Drug Administration (FDA) issued regulations requiring food and dietary supplement products to display labels declaring their nutrient content. The regulations specified the format for nutrition labeling as well as the reference values to use in declaring the nutrient content.

1. Pub. L. No. 101-535, 104 Stat. 2353 (1990).

2. Pub. L. No. 103-417, 108 Stat. 4325 (1994).

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The FDA now proposes to revise its food labeling regulations in order to improve the nutrition label's accuracy and usability.³ In particular, the proposed Food Labeling rule aims to do the following:

1. Update the nutrition label content based on the latest scientific evidence on health and nutrition captured in the Institute of Medicine (IOM) reports and Dietary Guidelines for Americans (DGA).
2. Update the nutrition label design to improve its use and readability.
3. Prompt manufacturers to reduce added sugars or to reformulate their products in order to maintain health claims under the updated Daily Value (DV) amounts.

The FDA makes an important effort to update its nutrition label content to reflect the best available science. The proposed rule will provide the public with more accurate nutritional information and will help consumers make healthier food choices and ultimately improve their health. With this rule, the FDA follows the principle set out in Executive Order 13563, which requires each agency to “ensure the objectivity of any scientific and technological information and processes used to support the agency’s regulatory actions.”⁴

Unfortunately, the FDA fails to apply this principle consistently. While the FDA makes a strong case that updating DV amounts would help consumers ensure adequate intake of vital nutrients, the agency provides little evidence that the proposed additional mandatory declarations and label format changes will result in consumers making healthier choices. On the contrary, the study commissioned by the FDA shows that a major proposed label change to increase the prominence and font size of calorie information has little impact on consumers’ choices. The FDA failed to test the effectiveness of other proposed label changes as well.

In addition, the FDA uses flawed assumptions to derive the rule’s benefit estimates and bases its calculations on a single unpublished study, casting doubt on its estimates’ validity. Even taking its flawed benefit estimates at face value, the FDA fails to maximize net benefits. The FDA opts for a two-year compliance period, even though the four-year compliance period offers higher net benefits and a fourfold reduction in regulatory burdens, which would translate into lower food prices for consumers.

Before issuing the final regulation, the FDA should take the following steps:

1. Obtain empirical evidence about whether its proposed label changes will have the expected beneficial health impact.
2. Reexamine its benefit estimates using peer-reviewed studies. In estimating benefits, the FDA should rely on the empirical studies clearly demonstrating the health impacts of proposed label changes. It should not simply assume that the proposed rule would produce the same type of benefits as the NLEA rule.
3. Separately estimate the marginal benefits of each proposed change and focus only on changes shown to have a positive impact.
4. Consider a broader range of regulatory alternatives.
5. Opt for a longer compliance period in order to maximize net benefits and to considerably reduce compliance costs.
6. Establish measures to monitor the rule’s health impacts.

3. US Department of Health and Human Services, Food and Drug Administration, “Food Labeling: Revision of the Nutrition and Supplement Facts Labels,” 79 Fed. Reg. no. 41 (proposed March 3, 2014): 11880–987.

4. Executive Order 13563—Improving Regulation and Regulatory Review, 76 Fed. Reg. no. 14 (January 18, 2011): 3821.

MORE EMPIRICAL EVIDENCE NEEDED TO SUPPORT THE RULE

The FDA hopes to achieve three different goals with this rule:

1. Update the nutrition label to provide more accurate nutritional information that reflects the latest IOM and DGA recommendations. The updated label may help consumers make healthier choices and could potentially reduce some chronic disease risks.
2. Improve readability by redesigning the label format. Better label design may make it easier for consumers to understand the nutritional information displayed on the label and increase the likelihood that they would use the nutritional information to make healthier choices.
3. Prompt producers to reformulate products. Given the new definition for fiber and updated DVs for some nutrients, some food manufacturers may reformulate their products in order keep the products' health claims. Similarly, some food manufacturers may respond to the requirement for added sugars disclosure by reducing the added sugars in their products. This would improve the healthfulness of products available to consumers.

Goal 1: Updating Nutrition Label Content

The proposed rule's first goal is to update the nutrition label content based on the latest available science. The FDA last updated the Nutrition Facts label in 2003 in response to the trans fat rule,⁵ and it last updated DVs for nutrients in 1995.⁶ The FDA's current proposal includes changing the definition for dietary fiber and updating DVs for some vitamins and minerals to reflect the latest IOM and DGA recommendations. In addition, the FDA proposes to include a new mandatory nutrient disclosure for "Added Sugars" in the updated nutrition label together with other label format changes. The proposed rule also drops the mandatory declaration requirement for vitamin A and vitamin C, but adds new mandatory declarations for vitamin D and potassium. The FDA identifies the latter as nutrients with potential public health significance, as some populations may be deficient in these nutrients.

Updated DVs for Nutrients

Currently, the label does not incorporate the latest dietary recommendations, which would reflect the changes in public health and the availability of new information about nutrients and reference intake values.⁷ Consequently, the label may be misinforming consumers about the healthfulness of their food choices. For example, the rule updates the DV for fiber based on IOM report recommendations.⁸ The new value is set at the level associated with the greatest reduction in risk of coronary heart disease. Similarly, the rule increases the recommended DV for potassium, which may reduce high blood pressure, and calcium, which may reduce osteoporosis.⁹ Studies indicate a low intake and possibly even a deficiency in these key nutrients in the general population.¹⁰

Since the FDA prescribes the label content, the regulation is necessary to correct the nutritional information. The updated nutritional label would provide consumers with more accurate information, help consumers make healthier food choices, and potentially reduce certain disease risks associated with deficiencies in key nutrients.

5. US Department of Health and Human Services, Food and Drug Administration, "Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims," 68 Fed. Reg. no. 133 (July 11, 2003): 41434–506.

6. US Department of Health and Human Services, Food and Drug Administration, "Food Labeling: Reference Daily Intakes," 60 Fed. Reg. no. 249 (December 28, 1995): 67164–175.

7. HHS FDA, "Food Labeling: Revision of the Nutrition and Supplement Facts Label," 11884.

8. *Ibid.*, 11911.

9. *Ibid.*, 11918–31.

10. *Ibid.*, 11918–19, 11922.

The FDA classifies added sugars as “sugars and syrups that are added to foods during processing or preparation.”¹¹ The added sugars line would be inserted in the label under the line for total sugar content. The agency justifies its decision by claiming that added sugars serve as the main source of calories for youths.¹² The FDA points out that, in contrast to foods with natural sugars, added sugars generally do not provide nutritional value. Further, it claims that added sugars may be displacing other nutrients or leading to overconsumption of calories.

The FDA provides little evidence that adding a separate line for added sugars would yield any health benefits. The IOM Dietary Reference Intakes report states that “added sugars are not chemically different from naturally occurring sugars.”¹³ As the FDA points out, “neither the 2010 DGA nor the IOM macronutrient report concluded that added sugars consumption from all dietary sources, in itself, increases obesity.”¹⁴ Similarly, the 2010 DGA states that added sugars do not increase obesity more than any other source of calories.¹⁵ Consequently, information related to added sugars is not a material fact and there is little reason for the FDA to require disclosure of different types of sugars.

To the degree that sugars add to calorie consumption or increase the risk of dental caries, the nutrition label already provides such information with the “Sugars” line. While it is possible that displaying added sugars may prompt consumers to examine the nutritional value of the product, the FDA provides no evidence that this will be the case. In contrast to other proposed nutrition label modifications, the FDA did not test whether providing information on added sugars would lead consumers to healthier food choices.

Empirical evidence for the potential impact of added sugars disclosure on consumer choices is mixed. Some studies show that negative disclosures lead consumers to switch to healthier choices. For example, in a study predating the NLEA, Edward Russo and his colleagues find that consumers switched to low-sugar versions when the sugar content of cereal was disclosed.¹⁶ In similar studies, which examined the impact of fat and cholesterol disclosures, consumers preferred healthier product versions.¹⁷ However, these studies examined the impact of disclosing previously unavailable nutrition information. In contrast, the requirement to disclose added sugars provides little new information but rather breaks down the source of sugars in food. It is possible that the requirement to show added sugars will not produce health benefits just as including “Calories from Fat” on the nutrition label had no impact on consumer choices.¹⁸

In addition, consumer responses to the disclosure may lead to unintended consequences. For example, several studies found that foods with “low-fat” labels may lead to excess consumption and increased obesity.¹⁹ The perceived healthfulness of the low-fat products reduced guilt associated with excess consumption. It also increased what consumers perceived to be an appropriate serving size. Similarly, consumers opting for products low in added sugars may increase overall consumption, as they would feel less guilty about eating such products. Additionally, consumers focusing exclusively on added sugars may overlook the overall sugar content and fail to constrain total sugar intake.

11. HHS, FDA, “Food Labeling: Revision of the Nutrition and Supplement Fact Labels,” 11902.

12. *Ibid.*, 11903.

13. Institute of Medicine (IOM) of the National Academies, *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients)* (Washington, DC: National Academies Press, 2002), 267.

14. HHS FDA, “Food Labeling: Revision of the Nutrition and Supplement Fact Labels,” 11904.

15. US Department of Agriculture and US Department of Health and Human Services, *Dietary Guidelines for Americans*, 2010, 7th ed. (Washington, DC: U.S. Government Printing Office, 2010).

16. J. Edward Russo et al., “Nutrition Information in the Supermarket,” *Journal of Consumer Research* 13, no. 1 (1986): 48–70.

17. Siva K. Balasubramanian and Catherine Cole, “Consumers’ Search and Use of Nutrition Information: The Challenge and Promise of the Nutrition Labeling and Education Act,” *Journal of Marketing* 66, no. 3 (2002): 112–27; Judith A. Garretson and Scot Burton, “Effects of Nutrition Facts Panel Values, Nutrition Claims, and Health Claims on Consumer Attitudes, Perceptions of Disease-Related Risks, and Trust,” *Journal of Public Policy & Marketing* 19, no. 2 (2000): 213–27.

18. Amy M. Lando and Serena C. Lo, “Single-Larger-Portion-Size and Dual-Column Nutrition Labeling May Help Consumers Make More Healthful Choices,” *Journal of the Academy of Nutrition and Dietetics* 133 (2013): 241–50.

19. Brian Wansink and Pierre Chandon, “Can ‘Low-Fat’ Nutrition Labels Lead to Obesity?,” *Journal of Marketing Research* 43, no. 4 (2006): 605–17; Kelly Geyskens et al., “The Backdoor to Overconsumption: The Effect of Associating ‘Low-Fat’ Food with Health References,” *Journal of Public Policy & Marketing* 26, no. 1 (2007): 118–25.

It is crucial that the FDA ensures that the label's additional content leads to better health outcomes before mandating its inclusion on the nutrition label. Including content that does not help consumers make healthier choices may crowd out the more vital content on the label and confuse consumers about their choices.²⁰ The FDA limits voluntary disclosures on the nutrition label for this reason.²¹

Mandatory Vitamin and Mineral Declaration

While the health benefits of consuming foods rich in mandatorily disclosed vitamins and minerals are not in doubt, the FDA does not consider the option of making these declarations voluntary. Manufacturers of foods rich in these nutrients already have strong incentives to declare the relevant vitamin and mineral content voluntarily. Thus, Athanasios Krystallis and Polymeros Chrysochou find that health claims increase consumer loyalty,²² while Klaus Grunert and Josephine Wills find that health claims increase consumers' positive attitude toward brands.²³ Manufacturers have strong incentives to find ways to educate consumers about the importance of these nutrients and to persuade consumers to increase consumption of nutrient-rich products. Studies by Pauline Ippolito and Alan Mathios and Pauline Ippolito and Janis Pappalardo show that food manufacturers are very effective at communicating to consumers the health information about nutrients through voluntary health claims.²⁴ Ippolito and Pappalardo note that voluntary health claims about calcium and other vitamins and minerals increased post-NLEA.²⁵

It is also important to keep in mind that consumer responses may moderate the impact of vitamin and mineral declarations. Siva Balasubramanian and Katherine Cole show that consumers are more likely to react to negative disclosures than to positive ones.²⁶ After the NLEA rule, consumers reduced their intake of high-fat and high-cholesterol foods (negative disclosure); however, their consumption of vitamin C decreased while calcium consumption remained unchanged (positive disclosures). Similarly, Russo and his colleagues find that consumers changed their purchasing behavior in response to disclosures for sugar content (negative) but not to disclosures for vitamins and minerals (positive);²⁷ Judith Garretson and Scott Burton find that fat content disclosures (negative) affected consumers' perception of the food's disease risks, while fiber content disclosures (positive) did not.²⁸

The FDA should test whether mandatory vitamin and mineral disclosures would have the desired health impacts. In addition, it should examine whether food manufacturers will provide such information voluntarily.

Goal 2: Label Redesign

In addition to updating label content, the rule proposes several changes to the way information is displayed on the label. Four of the proposed 13 changes would modify the content displayed on the label: (1) adding mandatory declaration for added sugars, (2) adding mandatory declaration for quantitative amounts for nutrients, (3) modifying the amount-per-serving declaration, and (4) removing the calories from fat declaration. The remaining changes mostly impact the label's formatting.

20. HHS FDA, "Food Labeling: Revision of the Nutrition and Supplement Fact Labels," 11888.

21. *Ibid.*

22. Athanasios Krystallis and Polymeros Chrysochou, "Health Claims as Communication Tools That Enhance Brand Loyalty: The Case of Low-Fat Claims within the Dairy Food Category," *Journal of Marketing Communications* 17, no. 3 (2011): 213–28.

23. Klaus G. Grunert and Josephine M. Wills, "A Review of European Research on Consumer Response to Nutrition Information on Food Labels," *Journal of Public Health* 15, no. 5 (2007): 385–99.

24. Pauline M. Ippolito and Alan D. Mathios, "Information and Advertising: The Case of Fat Consumption in the United States," *American Economic Review* 85, no. 2 (1995): 91–5; Pauline M. Ippolito and Janis K. Pappalardo, *Advertising Nutrition & Health: Evidence from Food Advertising 1977–1997*, Federal Trade Commission Bureau of Economics Staff Report (Washington, DC: Federal Trade Commission, 2002), <http://www.ftc.gov/reports/advertising-nutrition-health-evidence-food-advertising-1977-1997>.

25. Ippolito and Pappalardo, *Advertising Nutrition & Health*, 47.

26. Balasubramanian and Cole, "Consumers' Search and Use of Nutrition Information."

27. Russo et al., "Nutrition Information in the Supermarket."

28. Garretson and Burton, "Effects of Nutrition Facts Panel Values."

Table 1. Proposed Label Changes

Proposed change	Cited research
1. Increase the prominence of calories and the serving size information.	Lando and Lo*
2. Reverse the order of the "Serving Size" declaration and the "Servings Per Container" declaration.	
3. Right-justify the quantitative amounts of the serving size information.	
4. Change the "Amount Per Serving" declaration to "Amount Per ____," filling in the blank with a common household measure, e.g., "Amount Per 2/3 Cup."	
5. Remove the declaration of "Calories from Fat."	Lando and Lo*
6. Change the nutrient declarations and "% Daily Value" declarations on some products for some nutrients.	
7. Declare "Added Sugars" as an indented listing directly beneath the listing for "Sugars."	
8. Change the unit of measure for some nutrients.	
9. Declare the quantitative amounts (in addition to the % Daily Value) of mandatory and, when declared, voluntary vitamins and minerals.	
10. Modify the footnote.	
11. Require that all nutrients not currently highlighted in bold or extra bold type be highlighted in a type that is intermediate between bold or extra bold and regular type.	
12. Modify the presentation of the "% Daily Value" information by changing its position on the label and separating it from the list of nutrients with a vertical line.	
13. Add a horizontal line directly beneath the "Nutrition Facts" heading.	

* Amy M. Lando and Serena C. Lo, "Single-Larger-Portion-Size and Dual-Column Nutrition Labeling May Help Consumers Make More Healthful Choices," *Journal of the Academy of Nutrition and Dietetics* 133 (2013).

Source: US Department of Health and Human Services, Food and Drug Administration, *Analysis of Impacts* (March 3, 2014): 48–49, the other three changes come from the *Serving Size* rule.

The FDA relies on the growing behavioral economics literature to justify some of the proposed label changes. Some FDA-cited studies claim that consumers fail to think through the long-term health implications of their food choices when they purchase highly caloric foods with poor nutritional value.²⁹ They blame consumers' myopic decision-making for the growing obesity problem. The FDA reasons that it is not enough to simply inform consumers; the label format must also persuade them to make healthier choices.

The FDA hopes that, by increasing the salience of the information presented on the label, the proposed rule may help consumers overcome their myopic decision-making and increase their use of nutrition facts. For example, the FDA assumes that making calorie information more prominent would influence consumers to pay attention to the caloric content of the food.³⁰ Similarly, it assumes that disclosing added sugars would alert consumers if chosen foods are high in energy and poor in nutrition, and lead consumers to reconsider their choices.³¹

While the FDA cites some general behavioral economics research, it cites no studies to support its assumption that myopic behavior causes consumers to overlook the current nutrition label. In addition, the agency does not explain how its proposed changes would counter consumers' myopia. If consumers ignore the information presented on the current nutrition label because they fail to account for the long-term impacts of their diets, would they not ignore any additional or reformatted information on the new label?

In fact, the FDA-commissioned study cited in the regulatory impact analysis (RIA) finds that increasing the font size for calories had no impact on consumers' choices.³² Contrary to the FDA's assumption, increasing the prominence of calorie information did not make it more salient to consumers and did not lead to healthier choices. Nevertheless, the FDA decided to proceed with its proposal to increase the prominence of calories on the label.

29. US Department of Health and Human Services, Food and Drug Administration, *Analysis of Impacts* (hereafter referred to as "RIA") (March 3, 2014, available in the docket no. FDA-2012-N-1210 at regulations.gov): 6–8.

30. RIA, 8.

31. RIA, 7–8.

32. Lando and Lo, "Single-Larger-Portion-Size and Dual-Column Nutrition Labeling."

The same study finds that removing the “Calories from Fat” statement did not reduce consumers’ ability to judge the product’s healthfulness, as the statement duplicated information already available through total caloric content.³³ Similarly, consumers may ignore the added sugars disclosure, as the information is already contained in the current sugars declaration.

Of the thirteen proposed changes to the label design, only two are backed by cited research. The agency provides no other empirical evidence to support its proposed changes. The FDA justifies the changes by claiming that the improved design would increase label comprehension and use. While it references a product design manual in support of this claim,³⁴ the agency does not test whether its new label actually improves consumers’ comprehension or leads to healthier choices. Similarly, the FDA cites research that shows consumers’ confusion over serving size information, yet it does not test whether its new serving size declaration improves consumers’ comprehension.³⁵

A study by Lauren Block and Laura Peracchio lends support to the FDA’s decision to include quantitative amounts for vitamins and minerals in addition to the “% Daily Value” declaration.³⁶ The study shows that most consumers, including physicians, struggle to transform “% Daily Value” into quantitative amounts, yet physicians typically prescribe vitamin and mineral intakes in milligrams. Quantitative amounts may be particularly useful for at-risk consumers whose recommended vitamin and mineral intake is higher than average. However, the FDA does not cite this or any other study to support its decision.

To improve the rule’s transparency, the FDA should seek out and provide empirical support for each proposed change. Where such evidence is not available, the agency should commission studies that examine the impact of proposed changes. Better documented evidence would allow the general public to make better informed opinions regarding the rule and provide more useful feedback to the FDA regarding the rule.

Goal 3: Product Reformulation

The proposed rule’s third goal is to prompt manufacturers to reformulate their products in response to changes in DVs and the updated dietary fiber definition, as well as the new requirement to disclose added sugars.

The NLEA allows food manufacturers to make health claims about their products if they fulfill specified criteria. For example, some products may claim to be a good source of fiber or calcium if they contain sufficient amounts of these nutrients. As the new rule would change the DVs for fiber and certain vitamins and minerals, it would also change the amount of these nutrients required to continue claiming health benefits for products. Consequently, some manufacturers may have to reformulate their products to contain the newly required amounts of nutrients in order to maintain the health claims with regard to the nutrient or dietary fiber content of their products. Similarly, some manufacturers may decide to reduce the added sugars of their products due to that category’s greater prominence on the label.

Both the benefits and the costs of this portion of the rule depend on the share of products that manufacturers decide to reformulate in response to new label requirements. Yet the FDA simply assumes that 50 percent of manufacturers will reformulate their products to maintain health claims and 5–6 percent of manufacturers will reduce the added sugar content.³⁷ The agency provides no basis for its assumptions.

Better research on how manufacturers would respond to the new label requirements could provide some clues about the share of products that are likely to be reformulated. Such research would include determining the consumer demand for products with health claims and the value of health claims to manufacturers. The more consumers demand products with health claims, the more likely manufacturers are to reformulate their products. For added sugars, the relevant information would be the impact of negative health information disclosures on

33. *Ibid.*

34. RIA, 50.

35. RIA, 50.

36. Lauren G. Block and Laura A. Peracchio, “The Calcium Quandary: How Consumers Use Nutrition Labels,” *Journal of Public Policy & Marketing* 25, no. 2 (2006): 188–96.

37. RIA, 36–38.

consumer choices. The more consumers react to negative health disclosures, the more likely manufacturers are to reduce unhealthy ingredients.

Some studies indicate that food manufacturers value health claims. For example, Krystallis and Chrysochou find that health claims increase brand loyalty.³⁸ Similarly, Grunert and Wills find that health claims increase positive attitudes toward the brand.³⁹ In general, Julie Caswell and her colleagues and Hans van Trijp and Ivo van der Lans show that health claims became an accepted way for food manufacturers to communicate important nutritional information.⁴⁰

However, consumer responses to food manufacturers' decision to reformulate their products may moderate the rule's impact. The FDA assumes that consumers will continue to purchase the same brands even after manufacturers reformulate them. In contrast, Christine Moorman, Rosellina Ferraro, and Joel Huber show that the NLEA nutrition disclosure requirements have actually decreased the nutritional value of brand products.⁴¹ The authors explain the paradox by pointing to the trade-off between taste and nutritional value. They hypothesize that, because consumers value taste over nutritional value, they switch from healthier products to tastier ones, reducing the market share of healthier brands.⁴²

Alternatively, the shift to less nutritious brands may be driven by consumers' sensitivity to prices.⁴³ Only a small fraction of consumers care about nutritional value, while the majority remain neutral to nutrition disclosures. When manufacturers reformulate their products to increase their nutritional value, they incur additional costs, which they pass on to consumers in terms of higher prices. While the few health-conscious consumers may pay higher prices for healthier products, the majority switch to cheaper, less healthy products. Faced with reformulation costs and price-sensitive consumers, many food manufacturers may forgo health claims to maintain lower prices.

Research relevant to added sugars disclosure is similarly mixed. Some studies indicate that consumers react to negative disclosures by switching to healthier versions of products.⁴⁴ The FDA could examine the magnitude of the change to provide some indication for the potential number of products that may be reformulated. On the other hand, Moorman and her colleagues' study shows that higher prices resulting from reformulation costs may actually reduce the demand for products low in added sugars.⁴⁵ In addition, the research showing that the "Calories from Fat" statement had little impact on consumer choices may indicate that few manufacturers would choose to reduce sugar content in response to the mandated added sugars disclosure.⁴⁶

FLAWED BENEFIT ESTIMATES

The FDA arrives at its benefit estimates by assuming that the proposed rule's impact would be similar to the original NLEA regulation that took effect in 1994. Then it calibrates the estimated benefits by accounting for the differences between the proposed rule and the NLEA. The FDA starts with estimated benefits of the NLEA regulation and then adjusts the estimate for increases in population, increased use of nutrition labels, the share of products regulated by the USDA, and the likely smaller impact that the new Food Labeling rule will have compared to the NLEA rule. The FDA acknowledges that the new rule will likely have a smaller impact since it will make fewer changes to the nutrition label.

38. Krystallis and Chrysochou, "Health Claims as Communication Tools That Enhance Brand Loyalty."

39. Grunert and Wills, "Review of European Research."

40. Julie A. Caswell et al., "The Impact of New Labeling Regulations on the Use of Voluntary Nutrient-Content and Health Claims by Food Manufacturers," *Journal of Public Policy & Marketing* 22, no. 2 (2003): 147–58; Hans C. M. van Trijp and Ivo A. van der Lans, "Consumer Perceptions of Nutrition and Health Claims," *Appetite* 48, no. 3 (2007): 305–24.

41. Christine Moorman, Rosellina Ferraro, and Joel Huber, "Unintended Nutrition Consequences: Firm Responses to the Nutrition Labeling and Education Act," *Marketing Science* 31, no. 5 (2012): 717–37.

42. Christine Moorman, Rosellina Ferraro and Joel Huber, "From Consumer Information Regulation to Nutrition Competition: A Response," *Marketing Science* 31, no. 5 (2012): 747–55.

43. Brian T. Ratchford, "Suggestions for Further Research on Firm Responses to NLEA and Other Disclosure Laws," *Marketing Science* 31, no. 5 (2012): 744–47.

44. Balasubramanian and Cole, "Consumers' Search and Use of Nutrition Information"; Russo et al., "Nutrition Information in the Supermarket."

45. Moorman, Ferraro, and Huber, "Unintended Nutrition Consequences."

46. Lando and Lo, "Single-Larger-Portion-Size and Dual-Column Nutrition Labeling."

The FDA's model for estimating benefits takes the following form:

$$B_t = POP_t \times s_t \times \Delta W \times USE \times (1 - USDA),$$

where B_t is the estimated benefit from enacting the proposed Food Labeling rule; POP_t is the adult and adolescent population at time period t ; s_t is the ratio of the benefits attributable to the proposed Food Labeling rule to the benefits attributable to the NLEA rule; ΔW is the estimated gain in welfare resulting from enacting the NLEA rule; USE is the ratio of estimated use of the Nutrition Facts label under the proposed rule to the estimated use of the Nutrition Facts label under the NLEA rule; and $USDA$ accounts for the share of food products whose labeling is regulated by the USDA rather than the FDA.⁴⁷

The variables that have the greatest impact on the estimated benefits of the Food Labeling rule are the estimated welfare gains from the NLEA rule (ΔW) and the expected effect of the proposed rule relative to the effect of the NLEA (s_t). Since the FDA assumes that the proposed rule will have a beneficial health impact similar to the NLEA rule, the greater the estimated NLEA rule benefits, the greater the estimated benefits for the proposed rule. On the other hand, the FDA recognizes that the rules' impacts will not be identical. So it needs to calibrate the estimated benefits for the proposed rule by accounting for its differences from the NLEA rule.

The FDA uses a study conducted by Jason Abaluck to obtain the estimated benefits of the NLEA rule.⁴⁸ In the paper, Abaluck first estimates the changes in consumer purchases that resulted from the NLEA rule.⁴⁹ He then estimates consumers' willingness to pay for this information by estimating the price changes necessary to produce a similar change in consumers' choices.

The FDA accounts for the smaller number of changes that the proposed rule will enact compared to the NLEA rule in order to calibrate for the smaller impact that the proposed rule will likely have compared to the NLEA rule.⁵⁰ The NLEA rule changed 100 percent of the label content to achieve its health impact. The proposed rule would change only 33 percent of the content for single-column labels and 25 percent of the content for dual-column labels. The FDA therefore extrapolates that the proposed rule's impact would be 33 percent of the NLEA rule's impact for single-column labels and 25 percent of the impact for dual-column labels.⁵¹

The rule's benefit estimates have several problems. First, they rely on a single unpublished study. Abaluck's paper is available online as a working paper, but it is yet to be published in a peer-reviewed academic journal. The FDA uses no other studies for its estimates, nor does the agency attempt its own benefit estimates.

Furthermore, after issuing the NLEA rule, the FDA failed to monitor the regulation's impact. Nor did it conduct a comprehensive retrospective analysis on the validity of its original analysis and the effectiveness of the regulation in achieving its stated goals. Despite that, the new Food Labeling rule establishes no plans to monitor the impact of the proposed regulation.

Second, the FDA assumes that the proposed Food Labeling rule and the original NLEA rule will have similar impacts. Thus, it assumes that both rules address the same type of problem through the same type of action. However, the NLEA regulation addressed an information asymmetry problem. The rule increased the proportion of products displaying nutrition labels from approximately 60 percent to almost 100 percent.⁵² In addition, the rule standardized the disclosure information to make it easily comparable across different products. Consequently, the NLEA rule dramatically increased the information available to consumers.

47. RIA, 45–46.

48. RIA, 46.

49. Jason Abaluck, "What Would We Eat If We Knew More: The Implications of a Large-Scale Change in Nutrition Labeling" (working paper, October 17, 2011), http://economics.stanford.edu/files/Abaluck10_28.pdf.

50. RIA, 48–54.

51. To arrive at the mean estimate, the FDA multiplies these ratios by the share of label users and the share of total food products that single- and dual-column labels represent.

52. Balasubramanian and Cole, "Consumers' Search and Use of Nutrition Information"; Jayachandran Variyam, "Do Nutrition Labels Improve Dietary Outcomes?," *Health Economics* 17, no. 6 (2008): 696–97.

In contrast, the proposed rule adds little new information to the nutrition label. The biggest dietary culprits, such as calorie count, fat, sugar, and cholesterol, are already on the nutritional label. The new label will display updated DVs for carbohydrates, dietary fiber, and some vitamins and minerals. However, the Report of the Working Group on Obesity shows that few consumers use DVs when making food choices.⁵³ The rule's biggest change is to redesign the nutrition label for better readability. It is unlikely that rearranging label information would have the same health impact as disclosing previously unavailable nutrition information.

Third, the FDA assumes that the strength of an impact for a new regulation is proportional to the amount of content rearranged on the label. Yet the FDA provides no support for its assumption. In short, it assumes that all information on the label is equal and all disclosures have the same impact on shaping consumers' choices. Yet consumers generally focus on specific nutrients on the label and ignore the rest.⁵⁴

The FDA should provide better benefit estimates for the proposed changes. It should not base its estimates on the NLEA's impacts since the two rules promulgate qualitatively different labeling changes. While the NLEA regulation dramatically increased nutritional information available to consumers, the proposed rule makes only a few content updates and mostly changes the label's format. Instead, the FDA should empirically test the potential impact of each proposed change. Further, the agency should consider the marginal benefit of each proposed change separately instead of lumping all changes together. This would increase the rule's transparency and present a clearer picture of the rationale behind each proposed change. It would also allow the agency to focus on the changes that provide the greatest benefit and discard those that yield no results.

REGULATORY ALTERNATIVES

Under Executive Order 13563, agencies must consider a range of alternatives including nonregulatory measures and then tailor their regulations to impose the least burden on society.⁵⁵ The FDA fails on both counts.

Few Alternatives Considered

The FDA considers five alternatives including the proposed rule, but these are only minor variations of each other:

1. no federal regulatory action
2. proposed changes with two-year compliance period (selected option)
3. proposed changes with three-year compliance period
4. proposed changes with four-year compliance period
5. proposed changes with a DV for sodium of 1500 mg and 1900 mg

The FDA considers the first option—issuing no new regulation—superficially at best and provides no benefit estimates for continuing with the current nutrition label. The FDA simply assumes that there would be no additional benefits derived from the current regulation. Yet food companies, prompted by increasing consumer demand for healthier food choices, may well continue to improve their offerings under the current regulation.

The next three options differ only in the length of compliance time afforded to food manufacturers. The proposed rule offers manufacturers two years to comply with its requirements. The other two options allow three- and four-year compliance periods. A later compliance date considerably decreases the rule's costs but also delays the

53. US Department of Health and Human Services, Food and Drug Administration, *Calories Count: Report of the Working Group on Obesity* (March 12, 2004), <http://www.fda.gov/food/foodscienceresearch/consumerbehaviorresearch/ucm081696.htm>.

54. Sarah Campos, Juliana Doxey, and David Hammond, "Nutrition Labels on Pre-packaged Foods: A Systematic Review," *Public Health Nutrition* 14, no. 8 (2011): 1501.

55. Executive Order 13563, 3821.

rule’s potential benefits. The final option considers establishing a lower DV for sodium, but claims that evidence for its benefits is insufficient.

Other Alternatives That Should Be Considered

There are other options that the FDA should consider, ones that would yield benefits to consumers while limiting costs to producers. For example, labels could be updated only for DVs for nutrients. Another option is to make all vitamin and mineral declarations voluntary. In addition to providing a wider range of alternatives, these options would allow the FDA and the general public to compare the marginal costs and benefits of the different portions of the proposed rule and evaluate them separately.

The FDA should consider an option of only updating DVs for nutrients. Updating the label’s content to reflect the latest available science is important, and it makes a correction that only regulation can address, because current labeling reflects old regulatory standards. The FDA’s case for label redesign is considerably weaker; the agency presents scant evidence that its proposed label changes would have any impact. Limiting the rule to only DV updates would require manufacturers to make only minor changes to their labels, but it would produce the greatest benefit.

The FDA should also consider making all vitamin and mineral declarations voluntary. Manufacturers of products rich in vital nutrients will likely declare such nutrients without a mandate. They will also communicate the products’ benefits through health claims. Products poor in vitamins and minerals will simply leave the space blank. A less cluttered label would focus consumers’ attention on the other mandatory declarations with regard to calories, fat, and cholesterol.

Net Benefits Not Maximized

The rule should maximize the net benefits for the five regulatory options discussed in the analysis. Even taking the rule’s benefit estimates at face value, the rule fails to maximize net benefits (benefits minus costs). At a 3 percent discount rate, the four-year compliance option would provide \$29.6 billion in net benefits, while the FDA’s preferred two-year compliance option would provide \$29.1 billion in net benefits (see table 2). Yet the FDA does not explain its choice of a shorter compliance time.

Table 2. Summary of Net Benefits by Regulatory Option, 2013–2032
(in billions of 2011 dollars)

Option	Discount rate	Benefits	Costs	Net benefits
1. No new federal regulatory action	3%	\$0	\$0	\$0
	7%	\$0	\$0	\$0
2. Proposed rules, two-year compliance period	3%	\$31.4	\$2.3	\$29.1
	7%	\$21.1	\$2.3	\$18.8
3. Proposed rules, 3-year compliance period	3%	\$30.6	\$1.5	\$29.1
	7%	\$20.5	\$1.5	\$19.0
4. Proposed rules, 4-year compliance period	3%	\$30.2	\$0.6	\$29.6
	7%	\$20.1	\$0.6	\$19.5
5. Proposed rules, DV for sodium of 1,500 mg or 1,900 mg	3%	\$31.4	\$2.4	\$29.0
	7%	\$21.1	\$2.4	\$18.7

Source: US Department of Health and Human Services, Food and Drug Administration, Analysis of Impacts (March 3, 2014): 81.

The FDA's analysis shows that a longer compliance time reduces the rule's costs. Since manufacturers periodically update nutrition labels for their products, the new labeling requirements could be incorporated within these scheduled updates. Including the rule's requirements as part of coordinated updates considerably reduces manufacturers' compliance costs. An uncoordinated label change would cost manufacturers \$6,188 per product as opposed to only \$367 for a coordinated label change.⁵⁶

The longer manufacturers have to comply with the rule, the greater the share of products they can include in coordinated updates. The FDA's analysis shows that, with a two-year compliance time, 74 percent of private label food products, 78 percent of branded dietary supplements, and 84 percent of private label dietary supplements would have to undergo a costly uncoordinated label change.⁵⁷ Given a four-year compliance time, no food products or branded dietary supplements and only 49 percent of private label dietary supplements would undergo an uncoordinated label change.⁵⁸

Translated into dollar amounts, the two-year compliance option would cost \$2.3 billion while providing \$31.4 billion in benefits. In contrast, the four-year compliance option would cost \$0.6 billion while still providing \$30.2 billion in benefits. Thus, a two-year delay in the compliance date could result in an almost four-fold cost reduction, while only marginally reducing benefits.

The FDA should opt for a longer compliance time. Its benefit estimates are highly flawed, based on questionable assumptions and a single unpublished study. The agency provides little empirical support that proposed changes would be effective. Consequently, the rule's actual benefits are likely to be smaller. In contrast, the agency provides considerably better analysis of the proposed rule's costs. The fourfold reduction in costs resulting from a longer compliance time will reduce compliance costs to food manufacturers. Since manufacturers will likely pass on the additional costs to consumers, lower compliance costs will ultimately mean lower prices for consumers.

In addition, the FDA admits that the rule will significantly impact a large number of small businesses.⁵⁹ Under the Regulatory Flexibility Act, the FDA is required to consider flexible approaches to a rule in order to ease small businesses' regulatory burdens.⁶⁰ Similarly, Executive Order 13563 requires agencies to choose "among alternative regulatory approaches, those approaches that maximize net benefits."⁶¹ The four-year compliance option provides exactly the flexibility the Regulatory Flexibility Act requires by both maximizing net benefits and drastically reducing costs.

CONCLUSION

The proposed Food Labeling rule aims to improve the accuracy and usability of the nutrition label but with mixed results. The FDA makes a laudable effort to update the nutrition label information according to the best available scientific evidence. A more accurate nutrition label will allow consumers to make healthier food choices and will encourage adequate intake of vital nutrients. At the same time, the FDA provides little evidence that many of its proposed label format changes would have any beneficial health impacts. In addition, the agency bases its benefit estimates on a single unpublished study and several flawed assumptions, which put the validity of the estimates in doubt. Finally, the agency fails to choose the regulatory option that would maximize net benefits and considerably reduce the regulatory burdens on small businesses, despite being required to do so under the Regulatory Flexibility Act.

Before proceeding with the proposed rule, the FDA should commission studies testing the health impacts of each proposed label change. Further, the agency should reexamine its benefit estimates to reflect the benefits

56. RIA, 25.

57. RIA, 21.

58. RIA, 72.

59. HHS FDA, "Food Labeling: Revision of the Nutrition and Supplement Fact Labels," 11959.

60. Regulatory Flexibility Act, Pub. L. No. 96-354, 94 Stat. 1164 (1980).

61. Executive Order 13563, 3821.

to consumers stemming from the rule's actual impacts. The agency should provide separate estimates for marginal benefits of each proposed change and focus only on changes shown to have a positive impact. The agency should consider a broader range of alternatives, including an option that focuses only on updating DVs and an option that makes vitamin and mineral declarations voluntary. It should opt for longer compliance times to reduce the regulation's impact on small businesses and to reduce the costs passed on to consumers in the form of higher prices. Finally, it should make plans to monitor the rule's progress and impact on public health.